Storage conditions for the compositions of the present invention will depend on the electroprocessed materials and substances therein. In embodiments involving proteins, for example, it may be necessary or desirable to store the compositions at temperatures below 0°C, under vacuum, or in a lyophilized condition. Other storage conditions can be used, for example, at room temperature, in darkness, in vacuum or under reduced pressure, under inert atmospheres, at refrigerator temperature, in aqueous or other liquid solutions, or in powdered form. Persons of ordinary skill in the art recognize appropriate storage conditions for the materials and substances contained in the compositions and will be able to select appropriate storage conditions.

The compositions of the present invention and formulations comprising those compositions may be sterilized through conventional means known to one of ordinary skill in the art. Such means include but are not limited to filtration, radiation, and heat. The compositions the present invention may also be combined with bacteriostatic agents, such as thimerosal, to inhibit bacterial growth.

Formulations comprising the compositions of the present invention may be presented in unit-dose or multi-dose containers, for example, sealed ampules and vials, and may be stored in a freeze-dried (lyophilized) condition requiring only the addition of the sterile liquid carrier, for example, water for injections, immediately prior to use. Extemporaneous injection solutions and suspensions may be prepared from sterile powders, granules and tablets commonly used by one of ordinary skill in the art. Preferred unit dosage formulations are those containing a dose or unit, or an appropriate fraction thereof, of the administered ingredient. It should be understood that in addition to the ingredients particularly mentioned above, the formulations of the present invention may include other agents commonly used by one of ordinary skill in the art.

The compositions of the present invention may be packaged in a variety of ways depending upon the method used for administering the composition. Generally, an article for distribution includes a container which contains the composition or a formulation comprising the composition in an appropriate form. Suitable containers are well-known to those skilled in the art and include materials such as bottles (plastic and glass), sachets, ampules, plastic bags, metal cylinders, and the like. The container may also include a tamper-proof assemblage to prevent indiscreet access to the contents of the package. In

addition, the container has deposited thereon a label which describes the contents of the container. The label may also include appropriate warnings.

The present invention is further illustrated by the following examples, which are not to be construed in any way as imposing limitations upon the scope thereof. On the contrary, it is to be clearly understood that resort can be had to various other embodiments, modifications, and equivalents thereof, which, after reading the description herein, can suggest themselves to those skilled in the art without departing from the spirit of the present invention.

EXAMPLE 1

Fibroblast growth factor (FGF, obtained from Chemicon, Temecula, CA) was dissolved in a solution of matrix material comprised of type I collagen (80%), PGA (10%) and PLA (10%). The percentages refer to the weight of the materials with respect to one another. These materials were dissolved in HFIP at a final concentration of 0.08 gm per ml. Sufficient FGF was added to 1 ml of solution to provide an FGF concentration of 50 ng/ml of the collagen/PGA/PLA electrospinning solution. The material was electrospun into the shape of a cylinder onto the outer surface of a grounded and spinning 16 gauge needle about 25-35 mm in length. After application, the cylinder was sutured shut looping a suture around the outside of the construct and pulling tight to seal the ends. Alternatively, a hot forceps is used to pinch the ends together and literally heat seal the ends shut. These methods formed a hollow, enclosed construct. The construct was then surgically implanted within the vastus lateralis muscle of a rat. The construct was left in place for seven days and recovered for inspection. FGF in the matrix accelerated muscle formation within the electrospun matrix by promoting muscle formation within the wall of the electrospun cylinder.

EXAMPLE 2

Vascular endothelial growth factor (VEGF, obtained from Chemicon, Temecula, CA) was dissolved in a solution of matrix material comprised of type I collagen (80%), PGA (10%) and PLA (10%) as described in EXAMPLE 1. These materials were dissolved in HFIP at a final concentration of 0.08 gm per ml. Sufficient VEGF was added to 1 ml of solution to provide a VEGF concentration of 50 ng/ml of the collagen/PGA/PLA electrospinning solution. The material was electrospun to form a construct and implanted into a rat muscle

using the same procedures set forth in Example 1. VEGF increased the density of functional capillaries that were present throughout the construct. This was evidenced by the presence of capillaries containing red blood cells (RBCs).

EXAMPLE 3

Constructs of electroprocessed collagen and PGA:PLA copolymer, with VEGF spun into the matrix were prepared using 80% collagen and 20% PGA:PLA. The collagen and PGA:PLA were dissolved in HFIP at a final combined concentration of 0.08 gm per ml. Solutions were prepared in which different amounts of VEGF were added to 1 ml of the solution of collagen and PGA:PLA copolymer. Separate solutions were prepared containing 0 ng, 25 ng, 50 ng, and 100 ng each in 1 ml. Constructs were prepared for each solution by electrospinning one ml. The constructs were cut into smaller sections and placed in a phosphate buffer solution (PBS). Release of VEGF into the PBS was measured as a function of time by the ELISA method. The ELISA kit for VEGF was purchased from Chemicon International (part number cyt214) and the directions provided in the kit were followed to perform the ELISA. Samples were centrifuged to remove particulate matter and stored at –20 °C prior to use.

An identical construct was subjected to crosslinking by exposing it to glutaraldehyde vapor at room temperature and subjected to an identical ELISA assay. A sample of the electroprocessed construct was placed in a 100 mm tissue culture dish. A 35 mm tissue culture dish containing 1 ml of 50% glutaraldehyde was placed inside the 100 mm tissue culture dish. The lid of the 100 mm tissue culture dish was replaced and the sample was allowed to sit for 15 minutes at room temperature. The sample was rinsed in sterile water or culture media. The amount of VEGF (expressed in picograms per 1 mg of electrospun material) for the non cross-linked and cross-linked samples was measured at different times are presented in Figures 3 and 4, respectively.

In Figure 3 and Figure 4, the open diamonds represent release from the fibers electrospun from the solution containing PGA:PLA copolymer and collagen to which no VEGF was added. The open squares represent release from fibers electrospun from the solution containing PGA:PLA copolymer and collagen to which 25 ng of VEGF were added. The open circles represent release from the fibers electrospun from a solution containing PGA:PLA copolymer and collagen to which 50 ng of VEGF were added. The open triangles represent